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EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/373,585	Applicant(s) Ogura
	Examiner Frank Lu	Art Unit 1634

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *appeal brief filed January 27, 2003*.

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *6, 7, and 14-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *6, 7, and 14-21* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [X] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [X] All b) [ ] Some* c) [ ] None of:

1. [X] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s)
4) [ ] Interview Summary (PTO-413) Paper No(s). ___
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other

DETAILED ACTION

Response to appeal brief

1. In view of the appeal brief filed on January 27, 2003 and newly found rejections summarized herein, **PROSECUTION IS HEREBY REOPENED**. New ground of rejection are set forth below. The claims pending in this application are claims 6, 7, and 14-21. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

To avoid abandonment of the application, applicant must exercise one of the following two options:

file a reply under 37 CFR 1.111; or

request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1,131, or 1.132) or other evidence are permitted. See 37 CFR 1.93 (b) (2).

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 14-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Stern *et al.*, (US Patent 5,631,734, filed on February 10, 1994).

Stern *et al.*, teach method and apparatus for detection of fluorescently labeled materials. Figure 1a schematically illustrated a device used to detect fluorescently labeled targets on a substrate. Substrate 230 comprised a number of presynthesized probes on its surface 231. The substrate on which the sequences were formed were composed from a wide range of material, either biological, nonbiological, organic, inorganic, or a combination of any of these, existing as particles, strands, precipitates, gels, sheets, tubing, spheres, containers, capillaries, pads, slices, films, plates, slides, etc. The substrate had any convenient shape, such as a disc, square, sphere, circle, etc. The substrate was preferably flat but took on a variety of alternative surface configurations. For example, the substrate contained raised or depressed regions on which a sample was located. The substrate and its surface preferably formed a rigid support on which the sample was formed. The substrate and its surface were also chosen to provide appropriate light-absorbing characteristics (column 3, last paragraph).

A light source 100 generated a beam of light to excite the fluorescein labeled targets in the flow cell. The light source was an argon laser that generated a beam having a wavelength of about 488 nm, which in some embodiments were a model 2017 or model 161C manufactured by Spectra-Physics (column 5, fourth paragraph). In response to the excitation light, fluorescein labeled targets in the flow cell fluoresce light had a wavelength greater than about 520 nm. The fluorescence would.be collected by the microscope objective 140 and passed to optical lens 130. In practice, light collected by microscope objective contained both fluorescence emitted by the

fluorescein and 488 nm laser light reflected from the surface 231 (column 6, fifth paragraph). The light source above was considered as an exciting light source recited in claims 14 and 17.

Flow cell 220 was mounted on a x-y-z translation table 250. X represented the horizontal direction; y represented the vertical direction; and z represented the direction into and away from the microscope objective such that focusing was performed. Movement of the translation table was controlled by computer 190 (see third paragraph in column 5 and second paragraph in column 11). The x-y-z translation table was considered as a conveyor recited in claim 14.

Figure 1c illustrated an alternative embodiment of the fluorescence detection device which was similar to the embodiment shown in Figure 1a. Two color detection were required when two different types of targets, each labeled with a different dye, were exposed to a substrate synthesized with probes. In some embodiments, fluorescein and rhodamine dyes were used to label two different types of targets respectively. Typically, each dye would have a fluorescence peak at different wavelengths (column 8, fourth paragraph). According to the embodiment in Figure 1c, two fluorescence colors were detected by employing a second dichroic mirror, photomultiplier tube and associated lens, confocal pinhole and filter. The embodiment illustrated in Figure 1c was expanded by one skilled in the art to detect more than two fluorescence colors by employing an additional dichroic mirror, photomultiplier tube and associated lens, confocal pinhole and filter for each additional fluorescence color to be detected (column 9, second paragraph).

During the detection, data were acquired continuously along a line which was broken up into data points or pixels (column 9, third paragraph). The system operation was dependent on

several test parameters such as: a) temperature of the substrate; b) number of scans to be performed; c) time between scans; d) refocus between scans; e) pixel size; f) scan area; and g) scan speed (column 10, second paragraph). The scanning system were considered as the part of the detection system. Note that: (1) although the detection apparatus had been illustrated primarily herein with regard to the detection of marked targets, it would readily find application in other areas. For example, the detection apparatus disclosed herein was used in the fields of catalysis, DNA or protein gel scanning, and the like (column 16, last paragraph). In a Southern blot assay, hybridization signals could be scanned using this system; (2) although Stern *et al.*, did not directly state that the scanning system caused the exciting light to linearly scan the strip-like test piece in the longitudinal direction, this limitation was considered as inherent to the reference taught by Stern *et al.*, since the scanning system caused the exciting light to linearly scan the strip-like test piece along multiple axes thus the scanning system had an ability to linearly scan the strip-like test piece along the longitudinal direction during the scanning process; and (3) since this system was used to detect the interaction between unlabeled substrate and two different fluorescence-labeled targets (see column 8, fourth paragraph), this system had an ability to distinguish different fluorescence-labeled dyes.

Response to Arguments

I. In page 13, first paragraph of applicant's appeal brief, applicant argues that "the Examiner's rejection is internally inconsistent to the extent that it relies on "inherent disclosure" yet categorizes the scanning in a single dimension as a possible occurrence, i.e., "could be inherent" or "could be considered as one species of multiple axes" scanning. It is well-settled that

mere possibilities do not support inherence or prior art rejections. In re Robertson, 49 USPQZd 1949, 1951 (Fed. Cir. 1999).".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, the examiner agrees with applicant that "mere possibilities do not support inherence or prior art rejections". However, the scanning system taught by Stern *et al.*, causes the exciting light to linearly scan the strip-like test piece along multiple axes and the longitudinal direction is as one of species of multiple directions (multiple axes) during the scanning process taught by Stern *et al.*. In other word, the scanning system taught by Stern *et al.*, has an ability to scan the strip-like test piece along the longitudinal direction. Therefore, the scanning system causes the exciting light to linearly scan the strip-like test piece in the longitudinal direction is inherent to the reference taught by Stern *et al.*. Second, applicant does not provide any evidence to show why the scanning system taught by Stern *et al.*, can not used to scan the strip-like test piece in the longitudinal direction.

II. In page 14, last paragraph bridging to page 15, first paragraph of applicant's remarks, applicant argues that "[C]laim 14 describes a single axis of relative movement while the Examiner admits that Stern teaches a multiple axes device. In this connection, the Federal Circuit decision in In re Kotzab. 55 U.S.P.Q.Zd 1313, 1317 (Fed. Cir. 2000) is more applicable. In this recent case, the Federal Circuit reversed the USPTO which rejected a claim reciting a single temperature sensor when it was not clear whether the reference taught a single sensor or multiple sensors. Applicant submits that the facts of Kotzab are sufficiently analogous to the present situation to warrant withdrawal of the rejection. In the present situation the error of the rejection is more clear

than in Kotzab since in the instant case, the reference clearly uses multiple axis and not a single axis.".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, the Federal Circuit decision in *In re Kotzab*, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) is not related to the rejection since the examiner did not cited this case law in previous rejection. Second, the situation in *In re Kotzab*, 55 USPQ2d 1313, 1317 is nonanalogous to claims 14 and 17 of this instant case because the Federal Circuit decision was based on " [E]vens does not teach or suggest the use of **a single temperature sensor to control a plurality of flow control valves**" (see *In re Kotzab*, page 6, second paragraph) while Stern *et al.*, disclosed a scanning system that has an ability to cause the exciting light to linearly scan the strip-like test piece along multiple axes (**Apple vs Orange**). **Note that this system had a ability to cause the exciting light to linearly scan the strip-like test piece along single axe during the scanning process (function of an apparatus).**

III. In page 16, second paragraph of applicant's remarks, applicant argues "the Examiner has failed to discuss where the difference analysis is suggested. The Examiner merely describes how Stern includes optical devices that detect different fluorescent wavelengths. There is no further teaching of how samples are compared. In Stern, at no point is there an analysis means to compare scanning results for the comparison of hybridized DNA. Stern merely teaches a method of scanning an organism and provides no analysis mechanism for the comparison of hybridized DNA between organisms. The Examiner cannot argue that the DNA scanning mechanism in Stern can be used to determine DNA hybridization, when there is no evidence in Stern that it does so.".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, since the detection apparatus taught by Stern *et al.*, are used in the fields of catalysis, DNA or protein gel scanning, and the like (column 16, last paragraph). Such disclosure reasonably indicated that this system can be used to detect nucleic acid hybridization. For example, in a Southern blot assay, hybridization signals can be scanned using this system. Since this system can be used to detect different fluorescence signals, it can performed the functions of the analysis means as recited in claims 17 and 18. Second, applicant does not provide an evidence to show why the system taught by Stern *et al.*, can not perform the functions of the analysis means as recited in claims 17 and 18.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gleisner (US Patent No. 5,547,702, Published on August 20, 1996) in view of Tisone (WO 98/04358, published on February 5, 1998).

Gleisner teaches method for continuous manufacture of diagnostic test strips. The method comprised: (1) providing a web comprising a length of substrate having a width substantially the

dimension of the final length of the test strip being made; (2) placing on said substrate near one edge thereof a layer of material permeable to biological fluids, said layer having a width sufficient to place thereon a drop of biological fluid for treating; (3) continuously applying to the layer of permeable material an aqueous solution containing reagent detection chemicals capable of providing a detectable change in the presence of a predetermined analyte, said solution being applied in an amount to substantially saturate the permeable material; (4) drying the layer of permeable material to contain the reagent detection chemicals within said layer; and (5) cutting the web into predetermined shorter lengths containing a preset number of test strips for further processing (see last paragraph of column 1 and claims 1 and 5 in columns 5 and 6). In this method, the substrate 10 having a strip 11 of permeable material was continuously fed by a suitable conveyor past a coating station for applying the chemical reagents (see Figure 1 and last paragraph of column 3) wherein the chemical reagents comprised glucose oxidase, peroxidase and an indicator (see claim 2 in column 6).

Regarding claim 6, since Gleisner teaches to cut the web into predetermined shorter lengths containing a preset number of test strips for further processing, Gleisner discloses a cutting means which cuts the sheet-like substrate bearing thereon the plurality of specific binding agents in the first direction (cutting direction) into a plurality of strips as recited in the claim. Since Gleisner teaches that the substrate 10 having a strip 11 of permeable material is continuously fed by a suitable conveyor, Gleisner discloses a conveyor which conveys the sheet-like substrate relative to each other in a second direction which is substantially perpendicular to the first direction (cutting direction) as recited in the claim. Gleisner does not

disclose: (1) a plurality of applicators arranged at predetermined interval in a first direction relative to a sheet-like substrate each of said plurality of applicators respectively operable to apply one of the plurality of known specific binding agents on the sheet-like substrate, while the applicators apply the plurality of known specific binding agents, thereby applying the plurality of known specific binding agents in lines which extend in the second direction and are arranged at predetermined intervals in the first direction as recited in claim 6; and (2) the binding agents are formed in continuous lines across the sheet-like substrate as recited in claim 21.

Tisone teaches dispensing apparatus having improved dynamic range. This apparatus was used to apply one or more reagents to a test strip by different ways (see second paragraph in page 2 and first paragraph in page 4). As shown in Figure 9, three dispenser were arranged at predetermined interval to apply reagents to a test strip (see fourth paragraph of page 15). As shown in Figure 1, reagents flew directly onto the substrate to form a continuous line (see first paragraph in page 13).

Regarding claims 6 and 21, since Tisone teaches to use dispensers arranged at predetermined interval for applying reagents to a test strip, Tisone discloses a plurality of applicators arranged at predetermined interval in a first direction relative to a sheet-like substrate as recited in claim 6 wherein these applicators (ie., dispensers) are operable to apply one of the plurality of known specific binding agents on the sheet-like substrate (function of an apparatus). Since these dispenser are arranged in a direction that is perpendicular to width of the test strip, reagents are extended in the second direction (a direction in length of the test strip) and are arranged at predetermined intervals in the first direction (a direction of width of the test strip) as

recited in claim 6. Since reagents are applied onto the substrate to form a continuous line, the binding agents (ie, reagents) are formed in continuous lines across the sheet-like substrate as recited in claim 21.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made an apparatus as recited in claim 6 wherein the apparatus is capable to apply a plurality of known specific binding agents in lines which extend in the second direction using a plurality of applicators arranged at predetermined interval in a first direction relative to a sheet-like substrate so that a plurality of known specific binding agents are arranged at predetermined intervals in the first direction in view of prior art of Gleisner and Tisone. One having ordinary skill in the art would have motivated to do so because Tisone suggests that those skilled in the art in view of his invention would dispense a different kind of reagents using his method (see page 15, last paragraph) to make test strips with multiple test areas that are serially arranged so that multiple test would be performed using a single test strip (see page 2, second paragraph). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to make an apparatus as recited in claim 6.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gleisner (1996) in view of Tisone (February 5, 1998) as applied to claims 6 and 21 above, and further in view of Heyneker (US Patent No. 6,057, 100, filed on June 6, 1997).

The teachings of Gleisner and Tisone have been summarized previously, *supra*.

Gleisner and Tisone do not disclose that the specific binding agents are cDNAs as recited in claim 7.

Heyneker teaches a nucleic acid array wherein the nucleic acid can be cDNA (see column 8, lines 29-46) and the array is sectioned to a strip or test strip based on the requirement (see column 6, second paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made an apparatus recited in claim 6 wherein the specific binding agents are cDNAs in view of prior art of. Gleisner, Tisone, and Heyneker. One having ordinary skill in the art would have been motivated to do so because Tisone suggests that those skilled in the art in view of his invention would dispense a different kind of reagents using his method (see page 15, last paragraph) to make test strips with multiple test areas that are serially arranged so that multiple test would be performed using a single test strip (see page 2, second paragraph) and the simple replacement of one kind of specific binding agent from another kind of specific binding agent (i.e., cDNAs) during the process of making an apparatus as recited in claim 6 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Conclusion

6. No claim is allowed.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
May 21, 2003

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